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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,218	01/11/1999	SUSANNE M. BROWN	117-261	3436

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/117,218	Applicant(s) BROWN ET AL.	
	Examiner Quang Nguyen, Ph.D.	Art Unit 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 September 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 05 June 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: 13-22.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 2. NOTE: The phrase "a mutant herpes simplex virus comprising a non-functional gene, wherein said non-functional gene consists essentially of a non-functional gamma 35.4 gene" in the newly amended claims is unclear and potentially raises new matter issue. This is because the instant specification does not provide any guidance on a broad non-functional gene which is now limited to a non-functional gamma 35.4 gene, wherein the broad non-functional gene appears to refer to the same non-functional gamma 35.4 gene. Additionally, should Applicants intend to claim a method of treating a non-neuronal cancer using a mutant herpes simplex virus containing only a non-functional gamma 35.4 gene, this specific scope is narrower than the scope of the pending claims 13-22 that have been finally rejected on 12/05/01. This new limitation has not been recited in any of the previous pending claims. Therefore, such amended claims would require a new search and further consideration for their patentability .

Continuation of 5. does NOT place the application in condition for allowance because: the amended claims still read on the teachings of the prior arts of record. This is because of the open language of the term "comprising" in the amended claims 23-32 which encompass the utilization of a mutant herpes simplex virus containing other non-functional genes besides the non-functional gamma 35.4 gene to treat a non-neuronal cancer. Martuza et al. teach a herpes simplex virus vector that is altered in the gamma 34.5 gene and the ribonucleotide reductase to kill melanoma cells, pancreatic cancer cells, colon cancer cells, hepatoma cells among others in a subject. With respect to Applicants' argument that the inclusion of a modified ribonucleotide reductase gene is essential to a therapeutic vector of Martuza, and that Applicants believe Martuza teaches away from using a mutant having a gamma 34.5 gene mutation without a modification in the ribonucleotide reductase for non-neuronal treatment, Examiner respectfully finds Applicants' arguments to be unpersuasive for the following reasons. Firstly, with respect to ribonucleotide reductase negative mutants Martuza simply states "these mutants are attenuated for neurovirulence and less likely to propagate in the event of a fever in the infected host. Such characteristics are essential to a therapeutic vector which must be of attenuated neurovirulence and amenable to antiviral therapy in the event of viral encephalitis". However, Martuza does not teach anything that the inactivation of ribonucleotide reductase is essential or critical for the killing of non-neuronal cancer cells. It is also noted that the herpes simplex virus mutants having a gamma 34.5 gene mutation are also attenuated for neurovirulence (col. 6, lines 49-51) sharing this same property as ribonucleotide reductase defective mutants. Secondly, Applicants' belief that Martuza teaches away from using a mutant having a gamma 34.5 gene mutation without a modification in the ribonucleotide reductase for non-neuronal treatment is not considered to be factual evidence. Nowhere in the issued patent of Martuza, one finds negative teachings on a mutant having a gamma 34.5 gene mutation is not capable of killing non-neuronal cancer cells. It should be noted that Martuza teaches specifically that the presence of multiple mutations further reduces the possibility of reversion to wild-type pathogenicity of herpes simplex virus, so that brain and other tumor cells can be effectively killed without harming surrround normal brain (see col. 5, lines 35-47, and the claims).

DAVE T. NGUYEN
PRIMARY EXAMINER